

### Remarks

Reconsideration and withdrawal of the rejections set forth in the final Office Action dated March 7, 2011 are respectfully requested.

#### I. Double Patenting Rejections

Claims 1-38 and 40-60 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 56, 57, 59, 61 and 85-107 of co-pending U.S. application 10/137,664 in view of Tapolsky et al., WO 99/55312, hereafter "Tapolsky".

Claims 1-38 and 40-60 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 2, 7-9, 14-19, 21, 23-24, 36-40, 46, 53, 56-61 and 63-71 of co-pending U.S. application 10/359,546 in view of Tapolsky.

Claims 1-38 and 40-60 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-48 of co-pending U.S. application 10/848,538 in view of Tapolsky.

Claims 1-38 and 40-60 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-65 of co-pending U.S. application 12/491,068 in view of Tapolsky.

These rejections are traversed for the following reasons.

#### A. Legal Standard

In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define merely an invention that is merely an obvious variation of an invention claimed in the patent?. M.P.E.P. 804 II.B.1.

A double patenting rejection of the obviousness type is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. § 103 except that the patent principally underlying the double patenting rejection is not considered prior art. M.P.E.P. 804 II.B.1.

#### B1. Meeting the Legal Standard: Rejection over U.S. applications 10/137,664, in view of Tapolsky

The instant pending claims relate to, inter alia, a hydrogel film on a backing member, wherein the backing member erodes at a rate slower than the hydrogel film when placed in

a moist environment.

The claims in co-pending U.S. application 10/137,664 (hereafter "co-pending '664 application") are directed to a hydrogel composition comprised of an acrylate copolymer and a blend of a poly(N-vinyl lactam) with an oligomer.

Because the claims in the co-pending '664 application are silent as to erosion of the hydrogel and are silent as to erosion of a backing member, the Examiner looks to Tapolsky for its teaching of a bioadhesive device, wherein the adhesive layer and the backing layer are both erodible.

However, Tapolsky fails to show or suggest an arrangement wherein the backing member erodes at a rate slower than the hydrogel film when placed in a moist environment. Tapolsky notes that the kinetics of erodability of the device can be varied based on the components in films and the thickness and number of layers in the device (page 7, lines 6-12). Tapolsky, however, does not contemplate that the non-adhesive film (or backing member) erode more slowly than the adhesive layer, and expressly states otherwise in the passage at page 10, lines 7-13:

The pharmaceutical component may be included in either layer, although preferably, it is included in the adhesive layer, which is closest to the treatment site and which will have a slower erosion time, given that the backing layer protects the interior, adhesive layer and will typically erode first.

Thus, Tapolsky contemplates that the backing layer erodes before the adhesive layer, exactly the opposite of what is claimed. Accordingly, combination of the hydrogel composition as claimed in the co-pending '664 application with the erodible backing of Tapolsky fails to show or suggest a polymer/backing composition wherein the backing member has a slower rate of erosion than the hydrogel layer. Accordingly, withdrawal of the rejection is respectfully requested.

B2. Meeting the Legal Standard: Rejection over U.S. application 10/359,548 in view of Tapolsky

The claims in co-pending U.S. application 10/359,548 (hereafter "co-pending '548 application") are directed to a liquid composition that forms a film upon application to teeth. The liquid composition comprises polymers dissolved in a water-alcohol solvent. The hydrogel film that forms upon evaporation of the alcohol is "insoluble or slowly soluble" in

saliva.

The Examiner asserts it would be obvious to take the composition as claimed in the co-pending '548 application and combine it with the erodible backing of Tapolsky to arrive at the claimed composition. This rejection is misplaced, because it is not clear how the *water*-alcohol liquid composition as claimed in the co-pending '548 application can be combined with a *water*-erodible backing to form a device as taught by Tapolsky which is comprised of a hydrogel film and a backing. Placing the liquid composition, which is liquid by virtue of a *water*-alcohol solvent mixture, on the erodible backing to form a device as taught by Tapolsky would result in the liquid composition eroding the backing material during storage and prior to use, since the backing disclosed by Tapolsky is *water* erodible. Accordingly, the claimed composition is not an obvious variation of the claims in the co-pending '548 application and the disclosure of Tapolsky, and withdrawal of the rejection is respectfully requested.

B3. Meeting the Legal Standard: Rejection over U.S. application 10/848,538 in view of Tapolsky

The claims in co-pending U.S. application 10/848,538 (hereafter "co-pending '538 application") are directed to a composition comprising an acrylate polymer that is insoluble in water at less than pH 5.5 and a second acrylate polymer that is insoluble in water independent of pH. Because the claims in the co-pending '538 application are silent as to erosion of the composition and are silent as to the existence of a backing member, and, therefore, necessarily silent as to whether the backing member erodes or not, the Examiner looks to Tapolsky for its teaching of an bioadhesive device, wherein the adhesive layer and the backing layer are both erodible.

Applicants submit that the combination of the claims of the co-pending '538 application with the teaching of Tapolsky does not render the instant pending claims obvious, for at least the following reasons. First, the composition claimed in the co-pending '538 application comprises an acrylate polymer that is insoluble in water at certain pHs and a second acrylate polymer that is water insoluble at all pHs. It is not clear how this composition could be modified to be water erodible, given the polymers are water insoluble. Thus, it is not clear how a skilled artisan would modify the composition as claimed in the co-pending '538 application to be erodible, in accord with the suggestion in Tapolsky of a device that has a water-erodible polymer layer. Any modification to the composition

claimed in the co-pending '538 application that renders it water soluble so that it is water-erodible, as suggested by Tapolsky, would render the composition claimed in the co-pending '538 application inoperable for its intended purpose since the composition expressly requires water insoluble polymer.

Second, to the extent the Examiner proposes combining just the erodible backing from the teaching of Tapolsky with the composition in the co-pending '538 application, this combination would not arrive at the claimed composition. The combination of the composition from the '538 application with the erodible backing of Tapolsky results in a device wherein the backing layer is erodible yet the composition is not because of its water insoluble polymer. Thus, the combination does not arrive at the claimed composition, and certainly does not arrive at a composition wherein the backing member erodes at a rate slower than the hydrogel film when placed in a moist environment. In fact, the combination would achieve a composition wherein the backing member erodes faster than the composition - the exact opposite of what is claimed.

Accordingly, the pending claims are not an obvious variation of variation of the claims in the co-pending '538 application, and withdrawal of the rejection is respectfully requested.

Finally, and with regard to the double-patenting rejection over the co-pending '538 application, should the Examiner decide to maintain the rejection, Applicants request that the Office hold this rejection in abeyance until claims in this or the co-pending '538 application are found allowable. In the event that a provisional obviousness-type double patenting rejection is the only rejection remaining in this application, Applicants request that the rejection be withdrawn pursuant to MPEP 804 I.B.1. as the present application is the earlier filed application.

#### B4. Meeting the Legal Standard: Rejection over U.S. application 12/491,088 in view of Tapolsky

The claims in co-pending U.S. application 12/491,088 (hereafter "co-pending '008 application") are directed to a hydrogel composition comprising a discontinuous hydrophobic phase and a hydrophilic phase that is either continuous or discontinuous. Because the claims in the co-pending '088 application are silent as to erosion of the hydrogel and are silent as to the existence of a backing member and therefore necessarily silent as to whether the backing member erodes or not, the Examiner looks to Tapolsky for its teaching of an bioadhesive device, wherein the adhesive layer and the backing layer are

both erodible.

Applicants submit that the combination of the claims of the co-pending '088 application with the teaching of Tapolsky does not render the instant pending claims obvious, for at least the following reasons. First, the hydrogel composition claimed in the co-pending '088 application comprises a hydrophobic phase of a hydrophobic polymer, a plasticizer and a tackifying resin. These materials, especially the hydrophobic polymer and the tackifying resin, are materials that are generally water-insoluble and would not be expected to be erodible nor easily modified in a way to render them erodible. Thus, it is not clear how a skilled artisan would modify the hydrogel composition as claimed in the co-pending '088 application to be erodible, in accord with the suggestion in Tapolsky of a device that has a water-erodible polymer layer. Any modification to the hydrogel composition claimed in the co-pending '088 application that renders it water soluble so that it is water-erodible, as suggested by Tapolsky, would render the hydrogel composition claimed in the co-pending '088 application inoperable for its intended purpose.

Second, to the extent the Examiner proposes combining just the erodible backing from the teaching of Tapolsky with the hydrogel composition in the co-pending '088 application, this combination would not arrive at the claimed composition. The combination of the hydrogel composition from the co-pending '088 application with the erodible backing of Tapolsky results in a device wherein the backing layer is erodible yet the hydrogel composition is not because of its hydrophobic polymer and tackifying resin. Thus, the combination does not arrive at the claimed composition, and certainly does not arrive at a composition wherein the backing member erodes at a rate slower than the hydrogel film when placed in a moist environment. In fact, the combination would achieve a composition wherein the backing member erodes faster than the hydrogel film - the exact opposite of what is claimed.

Accordingly, the pending claims are not an obvious variation of variation of the claims in the co-pending '088 application, and withdrawal of the rejection is respectfully requested.

Finally, and with regard to the double-patenting rejection over the co-pending '088 application, should the Examiner decide to maintain the rejection, Applicants request that the Office hold this rejection in abeyance until claims in this or the co-pending '088 application are found allowable. In the event that a provisional obviousness-type double patenting rejection is the only rejection remaining in this application, Applicants request that the rejection be withdrawn pursuant to MPEP 804 I.B.1. as the present application is the

earlier filed application.

## II. The 35 U.S.C. § 103 Rejections

Claims 1-38, 40-41, 46-49 and 60 were rejected under 35 U.S.C. § 103 as allegedly unpatentable over Tapolsky in view of Roreger et al., U.S. Patent No. 5,458,745, hereafter "Roreger."

Claims 42-45 and 50-59 were rejected under 35 U.S.C. § 103 as allegedly unpatentable over Tapolsky in view of Roreger and further in view of Ye et al., WO 01/01958, hereafter "Ye."

Claims 50-59 were rejected under 35 U.S.C. § 103 as allegedly unpatentable over Ye in view of Tapolsky.

These rejections are respectfully traversed.

### A. The Cited Art

TAPOLSKY describes a delivery device for application to mucosal surfaces, the device comprising an adhesive layer and a backing layer. Both the adhesive layer and the backing layer are water-erodible. Tapolsky states that the adhesive layer has a slower erosion time than the backing layer (page 10, lines 9-13).

ROREGER describes a gel-film comprised of an anionic polymer and a cationic polymer that has good mechanical stability (Col. 2, lines 11-14; Col. 3, line 43). The gel-film is based on the premise of using a volative additive that prevents the anionic polymer and cationic polymer, which have opposing charges, from reacting during the formulation process (Col. 3, lines 16-23).

YE discloses an oral care delivery system comprised of a removable backing strip and a composition of an organosiloxane resin, a rheology modifier and an oral care substance. The oral care composition remains on the oral surface after the backing strip is removed.

### B. Legal Standard

To support an obviousness rejection, MPEP §2143.03 requires "all words of a claim to be considered" and MPEP § 2141.02 requires consideration of the "[claimed] invention and prior art as a whole." Further, the Board of Patent Appeal and Interferences recently

confirmed that a proper, post-KSR obviousness determination still requires the Office make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) and *CFMT v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003). It remains well-settled law that an obviousness rejection requires a suggestion of *all* of the claim elements.

An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). "Often, it will be necessary...to look to interrelated teachings of multiple [references]...and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known element in the fashion claimed[.]" *Id.* "[T]his analysis should be made explicit," and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

C1. Meeting the Legal Standard: Rejections based on Tapolsky in view of Roreger, with or without Ye

The Examiner asserts that it would have been obvious to provide a delivery device with an erodible backing layer and a polymer layer with active agent as taught by Tapolsky, and replace the polymer layer with active agent with the translucent composition taught by Roreger, which is a water-swellaible polymer, PVP and oligomer composition, because this film has good mechanical stability in swollen condition, high water absorption, handling stability (Office action, page 13, lines 2-12). Applicants respectfully submit that this proposed combination of teachings fails to show or suggest the claimed composition, and a *prima facie* case of obviousness has therefore not been established.

The claimed composition includes, *inter alia*, a hydrogel film on a backing member, wherein the backing member erodes at a rate slower than the hydrogel film when placed in a moist environment.

This feature of a backing member erodes at a rate slower than the hydrogel film when placed in a moist environment is not shown or suggested by either Tapolsky or Roreger, alone or in combination. Tapolsky describes an erodible device comprised of an adhesive film and a non-adhesive film (backing member). Tapolsky notes that the kinetics of erodability of the device can be varied based on the components in films and the thickness and number of layers in the device (page 7, lines 6-12). Tapolsky, however, does not contemplate that the non-adhesive film (or backing member) erode more slowly than the adhesive layer, and expressly states otherwise in the passage at page 10, lines 7-13:

The pharmaceutical component may be included in either layer, although preferably, it is included in the adhesive layer, which is closest to the treatment site and which will have a slower erosion time, given that the backing layer protects the interior, adhesive layer and will typically erode first.<sup>1</sup>

Thus, Tapolsky contemplates that the backing layer erodes before the adhesive layer, exactly the opposite of what is claimed.

There is nothing suggested in the cited documents, or by the Examiner in proffering the rejection, as basis for modifying the backing member to have a slower rate of erosion than the adhesive, hydrogel layer, particularly in view of the fact that Tapolsky specifically teaches the opposite of what is claimed. In view of this, a prima facie case of obviousness has not been established, and withdrawal of the rejection based on the combined teachings of Tapolsky and Roreger, with or without Ye, is respectfully requested.

## C2. Meeting the Legal Standard: Rejection based on Ye in view of Tapolsky

The Examiner asserts that it would have been obvious to whiten teeth using a device comprising an erodible backing and whitening agent-containing layer as taught by Ye and replace the whitening agent-containing layer with the composition taught by Tapolsky comprising a water-swellaible polymer, hydrophilic polymer and oligomer.

This combination of teachings does not show or suggest a device wherein the backing layer erodes in a moist environment at a rate slower than the hydrogel layer. Ye

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<sup>1</sup>For accuracy of the record, Applicants note that the Examiner appears to have misread this passage in Tapolsky. In the Office action, in the second to last full sentence on page 11, the Examiner states that, with regard to Tapolsky, "The adhesive layer containing the active agent will erode first and the backing layer has slower erosion time as it provides protection to the drug containing layer (page 10, lines 7-10)." This incorrectly summarizes what Tapolsky actually states.



does not disclose this claimed feature, and is utterly silent as to erosion. One must, then, look to Tapolsky for the 'erosion' feature. As discussed in Section C1 above, Tapolsky provides a general teaching that the kinetics of erosion of the device as a whole can be varied, by tailoring the components in the layers, the thickness of the layers, etc. The only passage in Tapolsky that describes erosion of the layers individually describes erosion of the backing layer at a rate faster than the adhesive layer – exactly the opposite of what is claimed. Thus, the combined teachings fail to show or suggest the feature of the claimed composition that the backing layer erodes in a moist environment at a rate slower than the hydrogel layer. Withdrawal of the rejection is respectfully requested

For the sake of accuracy of the record, Applicants wish to clarify the following sentence set forth on the Office action on page 11, lines 1-3 and on page 20, lines 9-11:

The adhesive layer further comprises polyethylene glycol, dihydroxy-polyethylene glycol and butylenes glycol up to 20%, which are the claimed oligomers (page 13, lines 10-14; page 14, lines 21-24; page 20, lines 5-11).

In fact, Tapolsky in the passage at page 13, lines 10-14 cites that cross-linking agents known in the art can be used to cross-link the film-forming polymer of the adhesive layer, where the cross-linking agents "may include glyoxal, propylene glycol, glycerol, dihydroxy-polyethylene glycol of different sizes, butylene glycol, and combinations thereof." The cross-linking agents do not include polyethylene glycol, nor is it stated that these agents can be up to 20%. Tapolsky in fact states that the maximum amount of a cross-linking agent should not exceed 5% molar equivalent of the polymeric material (page 13, lines 13-16).

The passage at page 14, lines 21-24 in Tapolsky is directed to plasticizers that can be included in the adhesive film, and recites a listing of suitable plasticizers. The passage at page 20, lines 5-11 in Tapolsky relates to methods of manufacturing the adhesive layer or device of Tapolsky by dissolving or suspending the components in a solvent. Tapolsky states that the "final solvent content is not more than about 20, preferably not more than about 15....% by weight of the total device." The Examiner's paraphrasing of these three passages together implies something Tapolsky in fact does not teach – a composition with a polyethyleneglycol component at 20 wt%. This error or incorrect implication is not material to the rejection at hand, or to Applicants' grounds for traversing the rejection. It is

corrected here for sake of clarity of the record and to ensure all parties understand the teaching of Tapolsky and realize that liberties in what a cited document teaches or suggests should not be unfairly taken in assessing patentability.

IV. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Favorable reconsideration and allowance of the pending claims is respectfully requested.

If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (650) 590-0734.

Respectfully submitted,

Date: June 3, 2011

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